

REMARKS**Rejection of Claims and Traversal Thereof**

In the November 18, 2008 Office Action,

Claims 16-29 were rejected under 35 U.S.C. §112, second paragraph;

Claims 8-14 and 30 were rejected under 35 U.S.C. §112, first paragraph; and

Claims 1-7, 15 and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sandborn et al, US Patent No. 6,166,044.

Applicants traverse these rejections and insist that none of the cited references alone or in combination defeat the patentability of the presently claimed invention which.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1 and 16-29 have been amended thereby obviating this rejection. Applicants request the withdrawal of this rejection under section 112, second paragraph.

Rejection under 35 U.S.C. §112, first paragraph

Claims 8-14 and 30 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Applicants disagree.

The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution. Clearly in the area of formulations of drug compositions for not only oral delivery but also for delivery via a suppository or enema, the application provides sufficient disclosure for one skilled in the art to recognize that applicants were in possession of the presently claimed invention. The present application provides a discussion for preparing such formulations on page 20 of the specification, and recreated below:

[0091] In the manufacture of a pharmaceutical composition according to embodiments of the present invention, the therapeutic agent(s) is typically admixed with, *inter alia*, a pharmaceutically acceptable carrier. The carrier must, of course, be acceptable in the sense of being compatible with any other ingredients in the pharmaceutical composition and should not be deleterious to the subject. The carrier may be a solid or a liquid, or both, and is preferably formulated with the therapeutic agent(s) as a unit-dose formulation, for example, a tablet, which may contain from about 0.01 or 0.5% to about 95% or 99% by weight of the therapeutic agent(s). The pharmaceutical compositions may be prepared by any of the well-known techniques of pharmacy including, but not limited to, admixing the components, optionally including one or more accessory ingredients. The therapeutic agent(s) are provided in an amount effective to achieve the desired pharmacological effect, as described above, and in a quantity appropriate to achieve the desired daily dose.

[0092] In certain embodiments, the compositions of the invention are designed to deliver the therapeutic agent(s) to the site of disease. For example, where the condition is Crohn's disease, an oral composition can be formulated to deliver the therapeutic agent(s) to ulcerated or inflamed tissue in the large intestine and/or the colon, releasing the therapeutic agent(s) along the length of the small intestine and the colon, and/or along the distal portion of the small intestine and in the colon. Similarly, where the disease condition is ulcerative colitis, an oral composition can be formulated to release the therapeutic agent(s) along the length of the distal portion of the small intestine and in the colon, or along the length of the colon. Moreover, where the disease site is in the colon (e.g., ulcerative colitis), the therapeutic agent(s) can be formulated as a suppository or an enema.

Notably, it is well settled in the law that examples are not required for each embodiment of the claimed invention. As explained in *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*:

“A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention”

424 F.3d 1336, 1345 (Fed. Cir. 2005) (citing *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995)).

Notably, an actual reduction to practice is not required for written description. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004) (“We of course do not mean to suggest that the

written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure . . .").

The Office bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992). Insofar as the written description requirement is concerned, that burden is discharged by “presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined in the claims.” *In re Wetheim*, 191 USPQ 90, (C.C.P.A. 1976). In the present situation, the specification contains a description of the claimed invention, as shown above, and thus the Office, in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient. *In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996). The Office has not met this burden.

Accordingly, applicants request the withdrawal of this rejection under section 112, first paragraph.

Rejection under 35 U.S.C. §103(a)

Claims 1-7, 15 and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sandborn et al, US Patent No. 6,166,044. Applicants insist that the cited reference does not in any way disclose, teach or suggest the presently amended claims.

To establish a *prima facie* case of obviousness the Office must show that the cited reference discloses, teaches or suggests all the elements of the recited claims. Meeting this requirement using the Sandborn reference is impossible.

Applicants claimed invention as recited in claims 1, 15 and 30 includes compositions that must include two separate groups of components, that being, a first group that includes at least one agent picked from the following list of therapeutic agents including

- azo-bonded 4-APAA compound;
- non-azo bonded 4-APAA compound;
- azo-bonded 5-ASA compound;
- non-azo bonded 5-ASA compound; and then

a second group is added to the composition which includes one of the following, that being,

- 4-APAA compound azo bonded to a 5-ASA compound or a combination of 4-APAA compound and a 5-ASA compound.

Thus, every composition of the presently claimed invention must include not only a **member from the first group** but also a **member from the second group that being either a 4-APAA compound azo bonded to a 5-ASA compound or a combination of 4-APAA compound and a 5-ASA compound**.

Clearly, the cited reference never considers such a combination. The information of using 5-ASA along with the nicotine is not sufficient to provide any guidance for the compositions of the present invention. Even in light of the *KSR* decision the Office is still required to present a *prima facie* case of obviousness, which clearly has not been established by the cited reference. Notably, the Office has not identified any objective or specific motivation or suggestion in the cited reference that would motivate one skilled to go in the direction of applicants' claimed invention. Clearly the use of a second group that includes a compound of either **a 4-APAA compound azo bonded to a 5-ASA compound or a combination of 4-APAA compound and a 5-ASA compound** is not a part of the Sandborn reference.

In light of the foregoing discussion and the fact that all of claimed limitations are not disclose or suggested by the cited reference, it is clear that the Office has not met its burden of establishing a *prima facie* case of obviousness. As such, applicants request the withdrawal of this rejection.

Petition for Extension and Fees Payable

Applicants request a one month extension and the fee for such an extension is being paid herewith by electronic transfer. In the event any additional fee is found due, the U.S. Patent and Trademark Office is hereby authorized to charge any additional amount necessary to the entry of this amendment to Deposit Account No. 13-4365 of Moore & Van Allen PLLC.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Spivack reconsider the patentability of the pending claims in light of the distinguishing remarks herein, and withdraw all rejections, thereby placing the application in condition for allowance. If any issues remain outstanding incident to the allowance of the application, Examiner Spivack is requested to contact the undersigned attorney at (919) 286-8089.

Respectfully submitted,

A handwritten signature in cursive script that reads "Marianne Fuierer". The signature is written in dark ink and is positioned above the printed name and title.

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